

**DOCKET NO: UPAP0025-100 (K1763)**  
**PATENT APPLICATION**

**Serial No.: 09/719,067**  
**Filed: August, 16 2001**

**IN THE CLAIMS:**

This listing of claims will replace all prior versions, and listings, of claims in the application.

Please cancel claims 1, 11, 26, 31 and 33; amend claims 2, 5, 9, 13, 18, 19, 23-25, 29, 30, 32 and 34, and add new claims 35-39.

**STATUS OF CLAIMS**

1. (canceled)

2 (currently amended) The method of claim 5 wherein said DNA molecule is administered by a route of administration selected from the group consisting of: intradermal, subcutaneous, intraperitoneal, intramuscular, and oral.

3-4 (canceled)

5 (currently amended) A method of delivering a protein to a macrophage cell or a cell of macrophage derived lineage of an individual comprising the steps of:  
administering to said individual by intramuscular injection at a site on said individual's body, a DNA molecule comprising a nucleotide sequence that encodes said protein, wherein said DNA molecule is a plasmid and wherein said DNA molecule is operably linked to a macrophage specific promoter and a polyadenylation signal that are functional in a macrophage cell and/or a cell of macrophage derived lineage, wherein said macrophage specific promoter is selected from the group consisting of a catalase promoter, a CD156 promoter, a M-CSFR promoter, a p73 promoter, and an FcγRI promoter, wherein said DNA molecule is taken up by a macrophage cell and/or a cell of macrophage derived lineage where said nucleotide sequence is expressed to produce said protein in said macrophage cell and/or a cell of macrophage derived lineage.

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6. (previously presented) The method of claim 5 wherein said polyadenylation signal is selected from the group consisting of: an SV40 polyadenylation signal and a bovine growth hormone polyadenylation signal.

7. (previously presented) The method of claim 5 wherein said DNA molecule is administered with a composition which facilitates uptake of said DNA molecule by a cell.

8. (previously presented) The method of claim 5 wherein said DNA molecule is administered with bupivacaine.

9. (currently amended) A method of delivering a protein to a lymphnode of an individual comprising the steps of:

- a) identifying said lymphnode that is to have protein delivered to;
- b) locating a site on said individual's body that is proximal to said lymphnode;
- c) administering to said individual at said site, a DNA molecule comprising a nucleotide sequence that encodes said protein, wherein said DNA molecule is a plasmid and wherein said DNA molecule is operably linked to a macrophage specific promoter and a polyadenylation signal that are functional in a macrophage cell and/or a cell of macrophage-derived lineage, wherein said macrophage specific promoter is from a human gene

wherein said DNA molecule is taken up by a macrophage cell ~~and/or a cell of macrophage-derived lineage~~ where said nucleotide sequence is expressed to produce said protein in said macrophage cell ~~and/or a cell of macrophage-derived lineage~~, and said macrophage cell ~~and/or a cell of macrophage-derived lineage~~ drains to said lymphnode, and delivers said protein in said lymphnode.

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10. **(original)** The method of claim 9 wherein said DNA molecule is administered by a route of administration selected from the group consisting of: intradermal, subcutaneous, intraperitoneal, intramuscular, and oral.

11-12. **(canceled)**

13. **(currently amended)** The method of claim 9 wherein said promoter is selected from the group consisting of: a catalase promoter, ~~a CD156 promoter~~, an M-CSFR promoter, a p73 promoter, and an FcγRI promoter.

14. **(original)** The method of claim 9 wherein said polyadenylation signal is selected from the group consisting of: an SV40 polyadenylation signal and a bovine growth hormone polyadenylation signal.

15. **(original)** The method of claim 9 wherein said DNA molecule is administered with a composition which facilitates uptake of said DNA molecule by a cell.

16. **(original)** The method of claim 9 wherein said DNA molecule is administered with bupivacaine.

17. **(previously presented)** The method of claim 5 wherein said protein comprises a secretion signal sequence.

18. **(currently amended)** A method of inducing an immune response against an immunogen in an individual comprising the step of:

administering to said individual at a site on said individual's body, a DNA molecule comprising a nucleotide sequence that encodes said immunogen operably linked to a macrophage specific promoter and a polyadenylation signal that are functional

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in macrophage cells ~~and/or cells of macrophage derived lineages~~, wherein said macrophage specific promoter is from a human gene,

wherein said DNA molecule is a plasmid and wherein said DNA molecule is taken up by a macrophage cell ~~and/or cells of macrophage derived lineage~~ where said nucleotide sequence is expressed to produce said immunogen in said macrophage cell ~~and/or cells of macrophage derived lineage~~ and an immune response mediated by said macrophage is generated against said immunogen.

19. **(currently amended)** The method of claim 18 wherein said DNA molecule further comprises

a nucleotide sequence that encodes an immunomodulating protein, wherein said DNA molecule is operably linked to a promoter and a polyadenylation signal that are functional in macrophage cells ~~and/or cells of macrophage derived lineages~~, and/or

a second DNA molecule is additionally administered to said site on said individual's body, wherein said second DNA molecule is a plasmid and said second DNA molecule comprising a nucleotide sequence that encodes an immunomodulating protein, wherein said second DNA molecule is operably linked to a promoter that is functional in macrophage cells and/or cells of macrophage derived lineages and a polyadenylation signal that is functional in macrophage cells ~~and/or cells of macrophage derived lineages~~.

20. **(original)** The method of claim 18 wherein said immune response targets a pathogen.

21. **(original)** The method of claim 18 wherein said immune response is a protective immune response.

22. **(original)** The method of claim 18 wherein said immune response is a therapeutic immune response.

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**23. (currently amended)** A method of modulating an individual's immune system comprising the step of:

administering to said individual at a site on said individual's body, a DNA molecule comprising a nucleotide sequence that encodes an immunomodulating protein, wherein said DNA molecule is a plasmid and wherein said DNA molecule is operably linked to a macrophage specific promoter and a polyadenylation signal that are functional in a macrophage cell ~~and/or a cell of macrophage derived lineage~~, wherein said macrophage specific promoter is from a human gene,

wherein said DNA molecule is taken up by a macrophage cell ~~and/or a cell of macrophage derived lineage~~ where said nucleotide sequence is expressed to produce said immunomodulating protein modulates said individual's immune system.

**24. (currently amended)** The method of claim 23 wherein said DNA molecule further comprises

a nucleotide sequence that encodes an immunomodulating protein, wherein said DNA molecule is operably linked to a promoter and a polyadenylation signal that are functional in macrophage cells ~~and/or cells of macrophage derived lineages~~ and/or

a second DNA molecule is additionally administered to said site on said individual's body, wherein said second DNA molecule is a plasmid and said second DNA molecule comprising a nucleotide sequence that encodes an immunomodulating protein, wherein said second DNA molecule is operably linked to a promoter that is functional in macrophage cells ~~and/or cells of macrophage derived lineages~~ and a polyadenylation signal that is functional in macrophage cells ~~and/or cells of macrophage derived lineages~~.

**25. (currently amended)** A method of eliminating cells in a lymphnode of an individual comprising the ~~steps~~ step of:

a) identifying a lymphnode containing cells to be eliminated;

b) locating a site on said individual's body that is proximal to said lymphnode;

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c) administering to said individual at said a site on said individual's body, a DNA molecule comprising a nucleotide sequence that encodes a cytotoxic protein, wherein said protein comprises a secretion signal sequence, said DNA molecule is a plasmid and said DNA molecule is operably linked to a promoter and a polyadenylation signal that are functional in a macrophage cell ~~and/or a cell of macrophage-derived lineage,~~

and wherein said DNA molecule is taken up by a macrophage cells ~~and/or a cells of macrophage-derived lineage~~ where said nucleotide sequence is expressed to produce said protein in said macrophage cells ~~and/or said cells of macrophage-derived lineage,~~

said macrophage cell ~~and/or a cell of macrophage-derived lineage~~ secretes or releases said cytotoxic protein in said lymphnode eliminating cells in said lymphnode.

26. (canceled)

27. (original) The method of claim 25 wherein said protein is a toxin.

28. (original) The method of claim 25 wherein said protein is ricin A chain or diphtheria toxin.

29. (currently amended) A method of delivering a desired protein to an individual comprising the step of:

administering to said individual at a site on said individual's body, a DNA molecule comprising a nucleotide sequence that encodes said desired protein, wherein said DNA molecule is a plasmid and wherein said DNA molecule is operably linked to a macrophage specific promoter and a polyadenylation signal that are functional in a macrophage cell ~~and/or a cell of macrophage-derived lineage~~, wherein said macrophage specific promoter is from a human gene,

wherein said DNA molecule is taken up by a macrophage cells ~~and/or a cells of macrophage-derived lineage~~ where said nucleotide sequence is expressed to produce said desired protein in said macrophage cells ~~and/or said cells of macrophage-derived lineage.~~

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30. **(currently amended)** The method of claim 25 wherein said promoter is a macrophage specific promoter selected from the group consisting of a catalase promoter, a M-CSFR promoter, a p73 promoter and an FcγRI promoter.

31. **(canceled)**

32. **(currently amended)** The method of claim 5 ~~4~~ wherein said DNA molecule is administered by intramuscular administration.

33. **(canceled)**

34. **(currently amended)** The method of claim 9 ~~4~~ wherein said DNA molecule is administered by intramuscular administration.

35. **(new)** The method of claim 5 wherein said macrophage specific promoter is selected from the group consisting of a M-CSFR promoter and an FcγRI promoter.

36. **(new)** The method of claim 9 wherein said protein comprises a secretion signal sequence.

37. **(new)** The method of claim 13 wherein said macrophage specific promoter is selected from the group consisting of a M-CSFR promoter and an FcγRI promoter.

38. **(new)** The method of claim 18 wherein said macrophage specific promoter is selected from the group consisting of a catalase promoter, a M-CSFR promoter, a p73 promoter and an FcγRI promoter.

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39. **(new)** The method of claim 18 wherein said macrophage specific promoter is selected from the group consisting of a M-CSFR promoter and an FcγRI promoter.